69 Ranck Avenue
Lancaster PA 17602
May 21, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville MD 20852

Dear Sir or Madame:

Consider this my written notice of my interest and my willingness to participate in the public hearings being held on June 28 and 29, 2000 in Gaithersburg, Maryland, on the regulation of over-the-counter drugs.

I am a teacher of middle school and high school students, with twelve years of experience. I would like to render my comments on the subject from the perspective of a teacher.

Sincerely yours,

Rosalie M. Gross

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OON-1256

APE 25

WHAT ILLS THE PILL HAS WROUGHT

By Dr. Jose A. Bufill. Special to the Tribune. Dr. Jose A. Bufill is a medical oncologist in South Bend, Ind.
March 8, 2000

The next time you huddle with your doctor to discuss the presumptive health benefits of the birth control pill, don't forget rule No. 1: Medicine is not an exact science. To make the simplest assertion about the risks or benefits of any medical intervention, a long and complicated process of testing, retesting and assessment needs to occur. Along the way, countless circumstances and events may introduce variables that bias the results in unpredictable ways. Even carefully planned, well-executed research can contain serious errors and lead to conclusions that are off the mark. And you can be sure that some in the medical profession are prone to use statistics much like a drunk uses a lamp post: for support, rather than for illumination.

They would like us to believe that oral contraceptives are a panacea.

The fact is that when these pharmaceuticals were first introduced to the U.S. market about 40 years ago, they accounted for significant morbidity. Despite every effort by drug companies and other interested parties to avoid bad press, the pill got off to a bad start. Many women were unable to tolerate their myriad side effects: depression and mood swings, facial hair and acne, back pain and headaches, to name a few.

Within a few years, doctors also began to recognize an increase in blood clots, strokes and heart attacks among the young women taking birth-control pills. When in the 1980s men were given diethylstilbesterol (DES), an oral contraceptive, to treat their advanced prostate cancers, they too experienced the same severe cardiovascular effects observed in women who took the pill. As a result, today DES is prohibited for cancer treatment in men, but its chemical kin are still ingested by millions of healthy women to avoid pregnancy.

Over the last 10 years, makers of the pill have quietly acknowledged their "toxicity" problem, changing the quantity and the quality of the pills' chemistry to make them more tolerable. And because the best defense is a good offense, pill makers vigorously supported attempts to identify possible fringe benefits to justify the pills' continued sale. They have claimed that oral contraceptives reduce the risk of all sorts of cancers in women, but the fact is that we just don't know that for sure, and probably never will. Even the pill's most optimistic advocates admit that any reduction in ovarian cancer risk, for example, occurs only if the pill is taken for five or more years. Any advantage in preventing ovarian cancer might be offset by the increased incidence of breast cancer associated with prolonged contraceptive use.

The American Cancer Society warns that the risk of developing breast cancer increases after birth-control pills are used, and the increased risk persists for 10 years after they are stopped. Perhaps that is why we have witnessed a such a sharp increase in the incidence of breast cancer in women over age 50 in the past 25 years.

Another problem with the data in support of the pill as a cancer preventative is that the studies suggesting benefit are "retrospective." They are sophisticated chart reviews: a glance over the shoulder at medical records to compare cancer incidences in women who said they took birth control with those who said they did not. Conclusions drawn from retrospective studies are notoriously unreliable and open to manipulation. The only conclusion to be made regarding the health benefits of oral contraceptives is that none can be made with confidence.

The naturally derived, high-dose contraceptives of the early years were better at preventing pregnancy, but there was a high price to pay, and the real debt may still be outstanding. Yet even today's third-generation "mini-dose" pill, a cocktail of laboratory-made hormones designed to reduce adverse effects, has been the subject of recent controversy.

Within the past year, several studies warned against an increased risk of cardiovascular problems in women taking these new substances. They also happen to be about half as effective in preventing pregnancy. And try as we may to correct past mistakes, we often end up making a bad situation even worse. If the drug companies that sell oral contraceptives do not recognize this based on their own objective appraisal of the data, perhaps the groundswell of lawsuits springing up around the world will help them sober up and see the light.

Consider also that most women take the pill not to treat a disease, but to manipulate a normal--and critically important--body rhythm, a delicately balanced hormonal ebb and flow that affects every organ system. Estrogens and progestins play important roles in the normal physiology of the brain, bones, liver, heart and blood vessels, immune system, skin and--lest we forget--the reproductive organs. Tiny amounts of hormone can and do affect the function of these tissues, so even the lower doses of synthetic hormones used in oral contraceptives are the physiologic equivalent of endocrinological carpet bombing. Only time will tell what long-term effects these drugs may have on the millions of young women who have taken them during a particularly susceptible period of their development.

A more accurate picture of the long-term effects of these substances on women's physical and emotional health may begin to emerge as the first generations of contracepting women begin to enter menopause and maturity. We can only hope that the physical harm done to women does not equal the social ills ascribed to contraceptives. Since birth control has become socially acceptable, the rates of teen pregnancy, sexually transmitted diseases, infant abandonment, illegitimate births and divorce have reached epidemic proportions.

The "age of the pill" has in fact become the "age of the ill": sick families, wounded women, fatherless children. This is the sobering reality that statistics do show: The pill has caused far more pathology than its advocates could ever dream of preventing.

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